

#### **DETAILED ACTION**

This office action is in response to the remarks and amendments filed on 7/3/2008. Claims 38, 40, 55, 63, 65, and 72-73 have been amended, and claims 39, 41, 56, 64, 66, and 74-75 have been cancelled. Claims 7-37 were previously cancelled. Accordingly, claims 1-6, 38, 40, 42-55, 57-63, 65, and 67-73 are pending.

#### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) filed on 7/3/2008 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered.

#### ***Terminal Disclaimer***

2. The terminal disclaimer filed on 10/6/2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,900,184 B2 has been reviewed and is accepted. The terminal disclaimer has been recorded.

#### ***Response to Arguments***

3. In view of the terminal disclaimer filed on 10/6/2008, the rejection of claims 1-6 and 38-75 for non-statutory obviousness-type double patenting over claims 1-90 of US 6,900,184 in view of Schlesinger et al. (US 5,763,480) is herein withdrawn. The double

patenting rejection over claims 1-23 over copending application 11/250,716 is herein in withdrawn in favor of allowance of the instant claims.

4. In view of the Applicant's arguments, the IDS submitted on 7/3/2008, and the Examiner's Amendment presented below, the rejection of claims 38-41, 55-56, 63-66, and 72-75 under 35 U.S.C. 112, first paragraph, for lack of enablement is herein withdrawn. See reasons for allowance for detailed explanation.

5. No claims remain rejected.

#### EXAMINER'S AMENDMENT

6. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Henry Gu on September 22, 2008.

The application has been amended as follows:

In claim 38, line 1, after claim; ~~delete~~ "1" and ~~insert~~ -2--.

In claim 38, line 2, after comprising; ~~delete~~ "an aminoglycoside selected from".

In claim 40, line 2, after comprising; ~~delete~~ "an aminoglycoside selected from".

In claim 63, line 3, after agent; ~~delete~~ "." and ~~insert~~ –; and in step (b) wherein an effective amount of buffer is used to adjust the pH.–.

In claim 72, line 4, after claim; ~~delete~~ "1" and ~~insert~~ –2–.

In claim 72, line 5, after and; ~~delete~~ "an aminoglycoside selected from".

In claim 40, line 5, after and; ~~delete~~ "an aminoglycoside selected from".

7. The following is an examiner's statement of reasons for allowance:

Claims 1-6, 38, 40, 42-55, and 57-61 are directed to pharmaceutical compositions comprising effective amounts of piperacillin or pharmaceutically acceptable salt thereof, tazobactam or pharmaceutically acceptable salt thereof, and an aminocarboxylic chelating agent selected from EGTA or CyDTA. Claims 62-63, 65 and 67-69 are directed to a process for the manufacture of a reconstitutable powder form of the pharmaceutical composition. Claims 70-73 are directed to a method of treatment or control of bacterial infections in a mammal, said infections being caused by periperacillin/tazobactam susceptible bacteria, comprising parental administration of the pharmaceutical compositions. The closest prior art is due to Cohen et al. (US 6,900,184 B2). Wyeth is the assignee of record for the instant application and US 6,900,184 B2. A properly executed terminal disclaimer has been filed to overcome the prior double patenting rejections of record, placing the claims in condition for allowance.

The inclusion of the aminocarboxylic chelating agent and buffer in the compositions comprising piperacillin and tazobactam allow for expanded compatibility with aminoglycosides, as evidenced by the paper by Desai et al. (see 7/30/2008 IDS)

**Comment [S1]:** Why is the 112, first rej withdrawn? Is it because there is evidence that they can actually stabilize the mixture in a given condition (the presence of EDTA and citric acid buffer)? If so, it is better to spell it out.

submitted by Applicants. Thus, the outstanding rejection under 35 USC 112, first paragraph is withdrawn, placing the claims in condition for allowance.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Claims 1-6, 38, 40, 42-55, 57-63, 65, and 67-73 are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Jody L. Karol/

Examiner, Art Unit 1617

/San-ming Hui/

Primary Examiner, Art Unit 1617